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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/572,515

03/17/2006

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EXAMINER

BAEK, BONG-SOOK

ART UNIT

PAPER NUMBER

4161

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DELIVERY MODE

08/18/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/572,515	<b>Applicant(s)</b> HOYANO ET AL.	
	<b>Examiner</b> BONG-SOOK BAEK	<b>Art Unit</b> 4161	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 June 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4 and 10-25 is/are pending in the application.
- 4a) Of the above claim(s) 10-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/17/2006, 6/26/2006</u> .                                    | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Status of Claims*

Claims 1, 2, 4, and 10-25 are currently pending.

### *Election/Restrictions*

Applicants' election of group I drawn to a composition comprising an anti-platelet agent and a 5-amidino-2-hydroxybenzene sulfonamide derivative and election of the following species: [4-[2-(5-amidino-2-hydroxybenzenesulfonylamino)ethyl]- 2'-methanesulfonylbiphenyl-3-yloxy]acetic acid as one species from 5-amidino-2-hydroxybenzene sulfonamide derivatives and cilostazol as one species from anti-platelet agents, in the reply filed on 6/26/2008 are acknowledged. Election was made **without** traverse in the reply filed on 6/26/2008.

Claims 10-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group or species, there being no allowable generic or linking claim. Claims 1, 2, and 4 are under examination in the instant office action.

### *Priority*

The instant application is a 371 of PCT/JP04/13982 filed on 09/16/2004 and claims benefit of foreign application filed on 9/19/2003. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). A certified copy of foreign application has been submitted on 3/17/2006.

The earliest effective U.S. filing date afforded the instantly claimed invention has been determined to be 09/16/2004.

***Information Disclosure Statement***

The information disclosure statements have been filed on 03/17/2006 and 6/26/2006. Since the IDS filed on 6/26/2006 includes all the references cited in the previous IDS filed on 03/17/2006, the IDS filed on 03/17/2006 has not been considered. "Yasuo Ikeda" reference in the IDS filed on 6/26/2006 is not considered because Applicant has not provided a copy of the reference.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, and 4 are rejected under 35 U.S.C. § 103(a) as being unpatentable over US patent 6,541,488 B1 (Issue date: 4/1/2003) in view of WO 02/28827 A1 (publication date: 4/11/2002), as evidenced by an English translation of WO 02/028827 A1 (part1 and part2), publication date: 11/04/2002. A copy of PCT application WO/2002/028827 is not supplied since applicant has a copy.

The instant invention is drawn to a composition comprising an anti-platelet agent (elected species: cilostazol) in combination with a 5-amidino-2- hydroxybenzene sulfonamide derivative (elected species: [4-[2-(5-amidino-2-hydroxybenzenesulfonylamino)ethyl]- 2'-methanesulfonylbiphenyl-3-yloxy]acetic acid).

US patent 6,541,488 B1 teaches a pharmaceutical composition containing one or more direct or indirect selective inhibitors of activated blood coagulation factor X (factor Xa) in combination with an anti-platelet aggregation agent such as cilostazol for the treatment of thromboembolic arterial diseases (abstract; column 2, line 16-line 33; and column 5, lines 5-31). However, it does not specifically teach 5-amidino-2- hydroxybenzene sulfonamide derivatives as a direct or indirect selective inhibitor of Xa.

WO/2002/028827 teaches that a 5-amidino-2-hydroxybenzene-sulfonamide derivative has a potent and selective inhibitory activity against factor Xa and is useful as preventive or therapeutic drugs for diseases whose onset is related to factor Xa such as thrombosis and embolism (abstract and p24, lines 8-24 of translation-part 1 of WO/2002/028827) and names the elected species of 5-amidino-2-hydroxybenzene-sulfonamide derivatives, [4-[2-(5-amidino-2-hydroxybenzenesulfonylamino)ethyl]- 2'-methanesulfonylbiphenyl-3-yloxy] acetic acid as a preferable embodiment (claim 9)

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It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine an anti-platelet agent and a 5-amidino-2-hydroxybenzene-sulfonamide derivative each of which is taught by the prior art to be effective for inhibiting thrombosis and/or embolism in order to get a composition comprising both agents to be used for the very same purpose. See *In re Kerkhoven*, 626 F. 2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). In addition, US 6,541,488 B1 provides motivation since it teaches synergistic effect of combination therapy of an anti-platelet agent with other direct or indirect selective inhibitors of (factor Xa) on treating thromboembolic diseases.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BONG-SOOK BAEK whose telephone number is 571-270-5863. The examiner can normally be reached 8:00-5:00 Monday-Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BONG-SOOK BAEK  
Examiner, Art Unit 4161

Bbs

/Patrick J. Nolan/

Supervisory Patent Examiner, Art Unit 4161